EXHIBIT C

BIOMEDICAL ENGINEERING CONSULTANTS

Hazard Analysis Report:
Bair Hugger Patient Warming System

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This report sets forth my findings relating to a hazard analysis which I was asked to perform with respect to the Bair Hugger patient warming system. The scope of this report is to examine the potential hazard raised by the use of the Bair Hugger device in orthopedic implant surgeries. My evaluation has led me to conclude that the Bair Hugger device presents an unreasonable risk in orthopedic operating rooms. I have based my opinions on:

- My examination of the device.
- My research into the device's history and environment of use.
- My research into the Defendant's interactions with the FDA.
- My review of Defendant's internal documents.
- My review of deposition testimony.
- My review of expert testing.
- My review of published research.

In totality, my review has led me to conclude that the Bair Hugger suffers from a troubling regulatory history, and that its design and marketing were unreasonably dangerous because the devices are more likely than not contributing to infections during orthopedic implant surgeries. I would recommend that the Bair Hugger not be used during these procedures. The opinions in this report are made to a reasonable degree of biomedical engineering certainty, which is to say that I conclude these opinions are more likely true than not true based on my professional judgment. If new evidence arises following this report, I will issue any necessary amendments to my opinions as appropriate.

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1. Background and Qualifications.

I have been a biomedical engineer for over 35 years. I completed my academic training at the bachelor (B.Sc., Electrical Engineering, 1972), masters (M.Sc., Electrical Engineering, 1973), and doctorate (Ed.D., 1983) levels at West Virginia University (WVU). I am currently a Principal at Biomedical Engineering Consultants, LLC in Houston, Texas. I am a registered Professional Engineer (P.E.) in Texas and certified in Clinical Engineering (C.C.E.) by the International Certification Commission as well as by the Healthcare Technology Commission.

In my professional capacity, I serve as the Chairman of the Medical Device Good Manufacturing Practice Advisory Committee of the U.S. Food and Drug Administration (FDA), and I serve on the FDA's Medical Device Advisory Panel. I was re-appointed to the Advisory Panel on December 31, 2013. I advise members of the FDA staff about issues related to applications submitted to the FDA for the 510(k) review process, device labeling, and special controls. Additionally, I founded and served as president of the Healthcare Technology Foundation, and I am currently the chairman of the Health Technology Training Group of the International Union for Physical and Engineering Sciences in Medicine. I am also a Fellow of the American College of Forensic Examiners Institute, of the American College of Clinical Engineering, and of the American Institute of Medical and Biological Engineering societies, and serve on the board of the Clinical Engineering Division of the International Federation of Medical and Biological Engineering. I have been awarded the FDA Commissioner's Special Citation, the American College of Clinical Engineering (ACCE) Lifetime Achievement Award, the ACCE/Association for Advancement of Medical Instrumentation 2008 Humanitarian Award, and the WVU Distinguished Professional Achievement and Service award. I held the academic appointments of adjunct Assistant Professor at Baylor College of Medicine from 1987–2010, and I have been adjunct Assistant Professor at the University of Texas, School of Public Health since 2008, and of Visiting Professor at the inner Mongolia People's Hospital.

I first became familiar working with medical devices, and electro-medical devices in particular, while I was an orderly in the operating rooms at WVU. Later, as a research assistant in the Department of Anesthesiology at the WVU School of Medicine, I worked with a wide variety of medical equipment including cardiac stimulators, thermal regulating devices used in regulating patient's temperature in areas such as the surgical theater as well as of new born babies in the neonatal intensive care units, among other equipment. Through

my academic affiliations at the Department of Anesthesia at the medical school at the West Virginia University and the Department of Pediatrics at the Baylor College of Medicine, I have participated in several clinical investigations of other types of electrical medical equipment, such as equipment measuring brain electrical stimulation, electromagnetic compatibility monitoring, telemedicine quality, blood pressure response to electrical stimulation, post cardiac surgery patient's temperature changes, and brain blood flow studies. The results of many of these investigations were published in peer-reviewed medical periodicals and journals.

From 1987 to 2008, I was the Director of the Biomedical Engineering Department at Texas Children's Hospital, where I also I served as chairman of the Medical Technology Evaluation Committee, which was responsible for evaluating technologies deployed at the point-of-care. As part of my work in this capacity and other evaluative functions, I have examined products to support and facilitate the evaluation and deployment decisions of various types of medical technology. The selection process typically involved reviewing the product, understanding the environment of use and potential risks, researching the regulatory background, and considering the evidence gathered and the conclusions reached in peer-reviewed scientific publications.

I also engage with manufacturers of medical devices and supplies, hospitals, and medical equipment vendors to analyze process improvements and work flow as each relates to medical technology. In this capacity, I visited design engineering and manufacturing facilities and plants of General Electric, Drager, Siemens, Mind ray, and Cardinal Health (IMED/Alaris). In that regard, I have had specific discussions regarding electro-medical device features and improvements and future product releases. In addition, I have served as engineering consultant for start-up companies that bring new products to the market. My responsibilities have generally included validating the engineering aspects of the devices, including the assessment of safety hazards. I have also assisted in the preparation of 510(k) Premarket Notification materials.

I have served as an expert in previous litigation involving medical products including surgical instruments, infusion pumps, thermo-regulating devices, and rehabilitation products (skin warmers, chairs, and their supplies) and patent infringements. My services are charged at a rate of $400 per hour except for deposition and court testimony where the rate is $450 per hour.

2. Methodology

2.1 Medical device hazard analysis.

My work has provided me with decades of experience in the methodologies of hazard analysis and risk assessment. Hazard analysis and risk assessment methodologies are strategies that are deployed within many of the manufacturing industries and government agencies, including those in the medical devices and pharmaceutical industries, where the proactive objective of such methods is to evaluate, mitigate, control, communicate and monitor exposure to potential risk therefore preventing undesired outcomes. Furthermore, this methodology proactively identifies the need for improvement based on collected data. It is an interactive hazard mitigation methodology, one that continues the process of assessing and controlling device's risk over the device's life. The hazard analysis begins with identification of and considering all of the device hazards associated with its intended use, reviewing the severity and probability of each of the hazards and accordingly ranking them in a risk scale. Following that, mitigation plans including alternative designs are being considered with the objective of elimination or reduction of the risk level to within acceptable level. This condition must be monitored throughout the use over the life cycle of the device and accompanied with clear communications about the residual risks to the user and the patient. The goal is to eliminate the hazard before it causes damage or negatively impact care outcomes. The level of residual risk is continuously evaluated over the device's life cycle, considering impact on patients.

2.2 Evaluating healthcare technology for safety considering design and the intended clinical environment for its use.

The principle of safety is the freedom from danger, risk, or threat of harm. Hippocrates oath, held sacred by physicians, incorporates such a tenet known as "Do no harm." It is a basic tenet that safe conditions should generally be provided in every segment of health care. In the surgical theater, patients undergoing surgical procedures are unable to defend for themselves, and the surgical staff must be made aware of a device's potential hazard. A prudent manufacturer of medical device will recognize these principles and design and manufacturer their product in such a way that when it used under intended conditions it will not compromise the clinical conditions or safety of the users nor of the patients.

Because the level of risk presented by medical devices can vary from low to high levels, the risk management program intensity can vary as well. The purpose of risk management is the continuous and adequate compliance with processes of identifying risks and evaluating their impact factor, so action can be taken to mitigate it and for the communication of residual risk, if any, to the users. The evaluation of conformity of the medical device requires that it validates that the design is appropriate for its intended use and verifies that the design output met the specified requirements. Hazard analysis and risk management can be conceptualized as four distinct steps. These steps act as repeating cycle as risks are continually reassessed[1]:

1. *Risk Identification*

    - Risk events and their relationships are defined.

2. *Risk Impact Assessment*

    - Consequences of risk events are assessed.

3. *Risk Prioritization Analysis*

    - Analytic rules applied to order identified events from most to least critical.

4. *Risk Mitigation*

    - Risks are mitigating by adequate planning, implementation, and progress monitoring.

When evaluating medical devices for patient risk, the investigator starts by understanding the device's function, operation, and environment of use. This includes an examination of the device, as well as an analysis of how its performance may impact the patient, the health care staff, and the overall environment. The investigator also considers the relative safety of alternative technologies. An investigation into the potential risk of a device is also aided by the investigator's professional experience, a review of related

[1] Adapted by Dr. Yadin David from Mitre, system engineering guide, https://www.mitre.org/publications/systems-engineering-guide/acquisition-systems-engineering/risk-management/risk-management-approach-and-plan)

published research, and evaluations by other qualified experts. To the extent possible, it also helpful to acquire information directly from the manufacturer of the device. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information. When a manufacturer is not open and forthright concerning safety information, an effective risk evaluation can be hindered. In this case, I have been provided access to confidential internal documents relating to the device and its development, rather than solely relying on publicly available information.

2.3 Hospital-based evaluation of medical devices.

Throughout my career, I have utilized the methodology of medical device risk assessment outside the field of litigation. As the director of the Biomedical Engineering Department over twenty-five years for hospitals in the largest medical center in the country, the Texas Medical Center, I organized and served as chairman of the Medical Technology Evaluation Committee (MTEC).

The purpose of the committee was to provide recommendations to the Texas Medical Center leadership regarding the deployment of medical products. MTEC membership included representatives from various stake holders ranging from physicians and nurses, to equipment buyers, biomedical engineers, facility engineers, and risk managers. To arrive at its recommendations the committee used similar process of evaluation described in this report.

I conducted risk analysis processes that included examination of the match between the device and the specific clinical use needs, reviewed current literature about the technology state of the art, obtained manufacturer's data about their device's performance, its safety, compliance and maintenance, performed bench testing, inquired experience of other users and compared available data about similar products. Manufacturer's data submitted by their representatives and the review of both bench and clinical testing were critical components of the evaluation process. This methodology allowed members of the MTEC committee to assess the risk to benefits ratio and thus their recommendation regarding the particular medical device or system.

3. Evaluating the Infection Risk Posed by the Bair Hugger

My purpose in this investigation was to examine the Bair Hugger from a biomedical engineering perspective to determine if the design and function of the device posed a risk

to patient safety. Specifically, my focus was on the risk of contributing to the development of post-surgical infections in orthopedic surgeries. The Bair Hugger could pose a risk in this area in two ways.

First, the Bair Hugger would pose an infection risk if it disrupted or interfered with the ventilation system used in the clean environment of an orthopedic operating theater. Despite advances in infection control over the past several decades, orthopedic implant surgeries remain extremely sensitive to infections. One of the measures used to combat infections in orthopedic surgeries was the design and construction of surgical theater suites equipped with directional filtered airflow. These systems are variously referred to as a laminar flow design, a unidirectional airflow design, or a positive-pressure room design. The purpose of these clean environment systems is to create a constant flow of freshly filtered air directed downward from the room ceiling towards the patient and on to the return vents where it is exited, creating a clean field of air over the patient to help prevent bacterial and other airborne contamination from reaching the surgical site. The concern lies in the fact that the Bair Hugger exhausts heated air, which can carry contaminated pathogens particles back up to the surgical site. If convection caused by the heated Bair Hugger air carries particles into the surgical site area -- contrary to the intended flow of operating room air -- those particles will not be sterile and will deposit pathogens into the surgical site.

Secondly, the Bair Hugger system could also pose a risk if the devices were harboring and incubating colonies of pathogenic bacteria and introducing that bacteria into the operating room air currents. The safety claims for the device hinge on the use of a “high efficiency” .2 micron filter to prevent this risk. If inadequate filtration were used, it could allow the device to gather floor-area bacteria into the internal structure, incubate bacterial colonies in the machine and the corrugated hose, and blow these pathogens into the operating room air.

After a review of an extensive body of literature, documents, testimony, expert testing, as well as inspection of the device itself, it is my biomedical engineering opinion that the potential airborne contamination risk from the device is credible and supported by experimental and clinical evidence. As discussed more fully below, it is my opinion that the device more likely than not contributes to infections during its use in orthopedic implant surgeries.

4. Understanding the Bair Hugger and the Areas of Risk

4.1 Description of the Bair Hugger and its operation.

The Bair Hugger first appeared on the market in 1987, designed and manufactured by Augustine Medical, Inc. Over the years, the company changed ownership and names, known as Augustine Medical, Arizant Healthcare, and 3M. (For convenience, this report will refer to these entities as "the Defendant.") The device was first marketed to treat the discomfort of post-operative hypothermia.[2] Within the 510(k) regulatory submission document to the FDA dated September 14, 1987, the Defendant described the device for use outside the operating room as follows:

> The Bair Hugger System is designed to treat the discomfort postoperative hypothermia by creating a personalized environment of comforting warm air. The Bair Hugger System consists of two parts; the Heater/Blower Unit (see enclosure 3) and the Bair Hugger ™ Patient Cover (see accompanying photographs). The Patient Cover is attached to the air hose by a simple wrap-around tape…The Bair Hugger Cover creates a "micro-environment" of increased ambient temperature, that *surrounds* and contacts the patient *on* all non-dependent surfaces except the head.[3]

However, subsequent models of the Bair Hugger were marketed for use during operations. The Defendant also began to market the Bair Hugger for use in ultra-clean orthopedic surgeries. The Bair Hugger device is described in the Department of Health and Human Services, Food and Drug Administration, Establishment Inspection Report (EIR) dated November 17, 2010, as "forced air patient warming systems used in hospitals and medical centers to prevent hypothermia during and after surgical procedures."[4] In addition, The 3M Bair Hugger Model 750 Warming Unit Service Manual (No. 202522A)[5] further describes in the Introduction section:

> You can use the Model 750 temperature management unit in all clinical settings where the patient may become too warm or

[2] 1987-09-14 510(k) Notification Letter - 3MBH00047858
[3] *Id.* - 3MBH00047859.
[4] *Id.* - 3MBH00048069.
[5] Bair Hugger 750 Warming Unit Service Manual.

> too cold including the operating room to provide patient temperature management.

Although within this description it states that "Warm air generated in the unit," the fact is that the Bair Hugger warms ambient room air that is suctioned into the device at or near the operating room floor level. The unit then forces this air to flow over heating element that increases the air temperature, pushing it into the patient blanket through a connecting hose. The warmed forced air is then pushed out of the blanket through the perforations provided for this purpose on the blanket side that faces the patient where it is finally released into the surrounding environment around the blanket near the surgical site.

4.2 Examination of the Bair Hugger device.

I conducted an inspection of an exemplar Bair Hugger device model 750, S/N 21441, Rev N. The exemplar device was purchased as used through the website e-Bay.com. During the device interrogation, I found out that the hour meter shows that the device previously has been in operation for a total of 5260.58 hours. The device archive also show that five (5) fault code events were logged in its memory log. The oldest event occurred about 1,939 hours previous to this examination, the second event occurred about 447 hours previous to this examination and the other three events just prior to the initiation of this examination.

Despite the fault codes, the self-test and the over temperature test both passed successfully indicating that the device was ready for use. While this exemplar device was functional for my purposes -- which was to understand the basic operation and mechanisms of the device -- I was aware that in light of the device's advanced age and presence of fault codes, this device may not be representative of the actual performance and tolerances of a properly functioning Bair Hugger unit in terms of airflow or heat delivery.

[redacted]

[6] 2009-10-15 internal email – 3MBH00002647

[redacted]

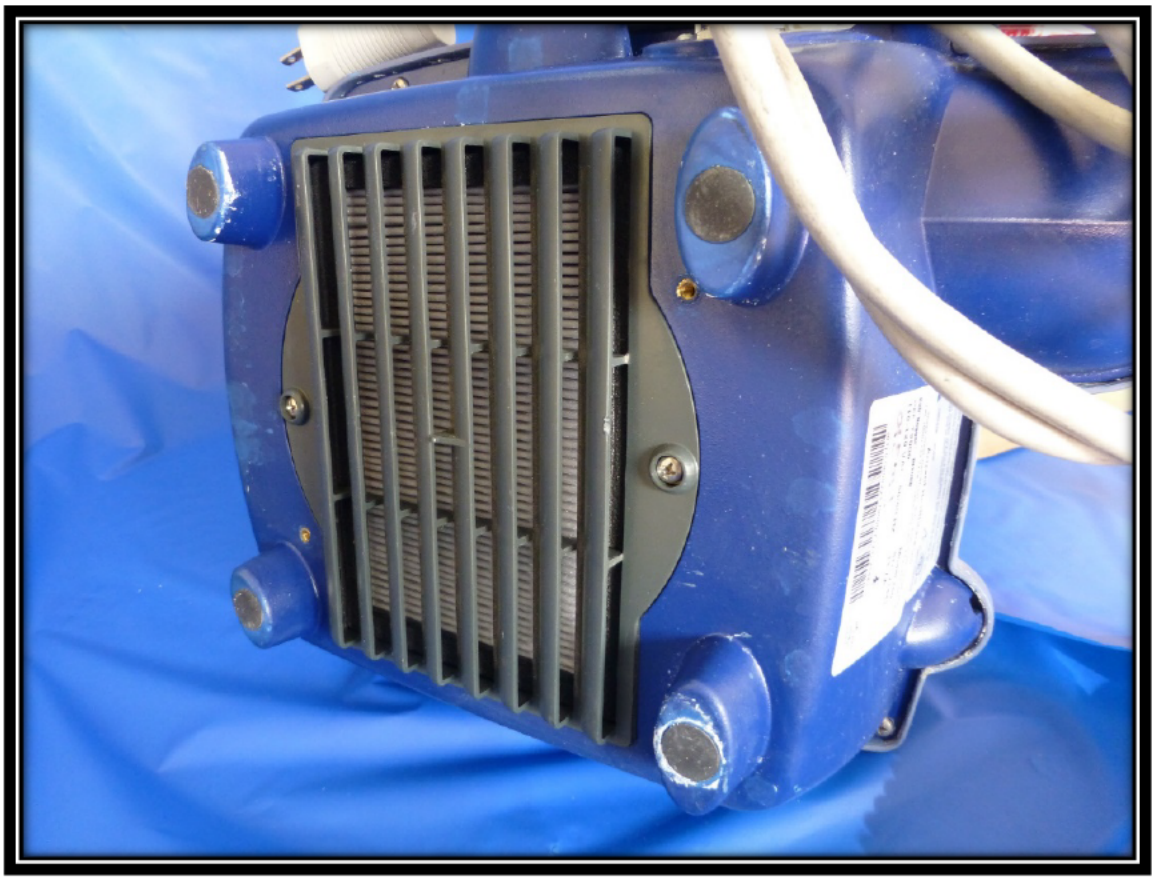
Using infection control safeguards (washing hands before and after handling of the device, covered surfaces, disinfecting tools, wearing gown, mask, cap and examination gloves) I proceeded to unpack and photograph the device and its accessories, including the removal of the filter holder at the bottom of the device facing the floor, as well as the filter itself. The filter is located within the device at a distance of about 0.75" (inch) above the operating room floor. The filter size is about 6"x4"x$^{3}/_{4}$" (inches) having a fan behind it to draw room air into the device. Room air from the surrounding of the Bair Hugger device is suctioned into the device through the filter and continuing over the heating element of the device.

Towards the top of the device the operating controls are visible and carrying handle arches over that. On the side of the device an IV pole clam provides means to mount the device to an IV pole, and at the back side of the device a connector of about 2$^{1}/_{4}$" (inches) in diameter provides the means for connecting the corrugated and flexible hose, containing

[7] 2008-12-02 internal email – 3MBH00024592
13 3M Bair Hugger™ Model 750 Warming Unit Service Manual No. 202522A, 07/13

electrical wiring down to the patient blanket. Through this hose the warmed air is pushed through the heating apparatus inside the device towards the blanket that is placed over the patient.

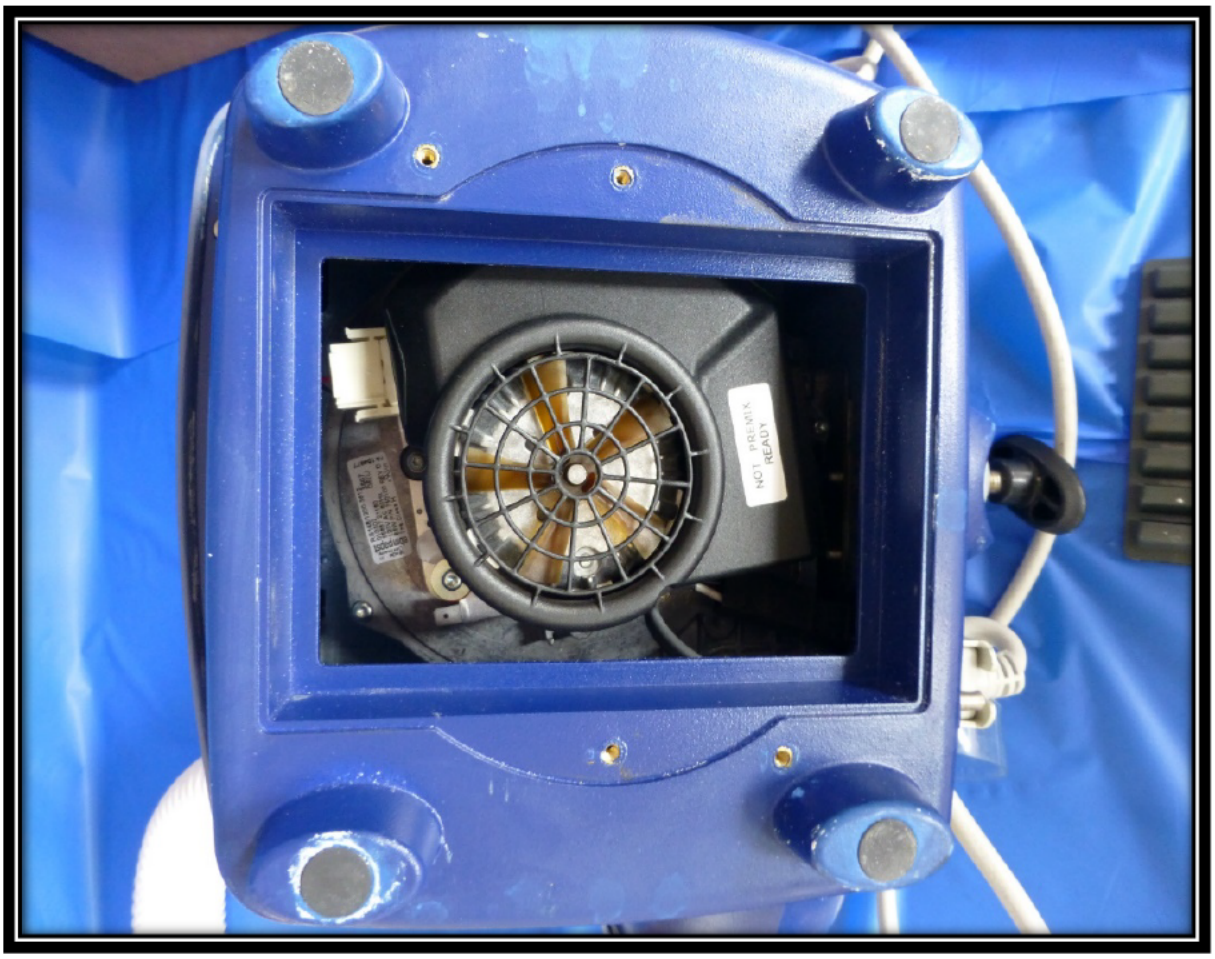
From the blanket the warmed air is forced out into the operating room environment at about hip level height of the surgeon while operating on the patient. The warmed air is forced out of the blanket through minute holes, perforations, designed into the blanket lower side that is facing the patient. The electrical wiring placed inside the corrugated hose are used for transmitting temperature sensor information collected at the end of the hose back to the device-controlling electronics.



Above: Bottom view of the Bair Hugger showing air intake and filter.

When I opened the air intake and removed the air filter, it was immediately obvious that dust particles were present on the filter and the blades of the fan behind it. This dark and warm cavity containing the filter housing and the fan motor can serve as hospitable environment for harboring and incubating colonies of pathogenic bacteria and introducing that bacteria into the flow of air delivered to the patient's blanket. [redacted]

[redacted]

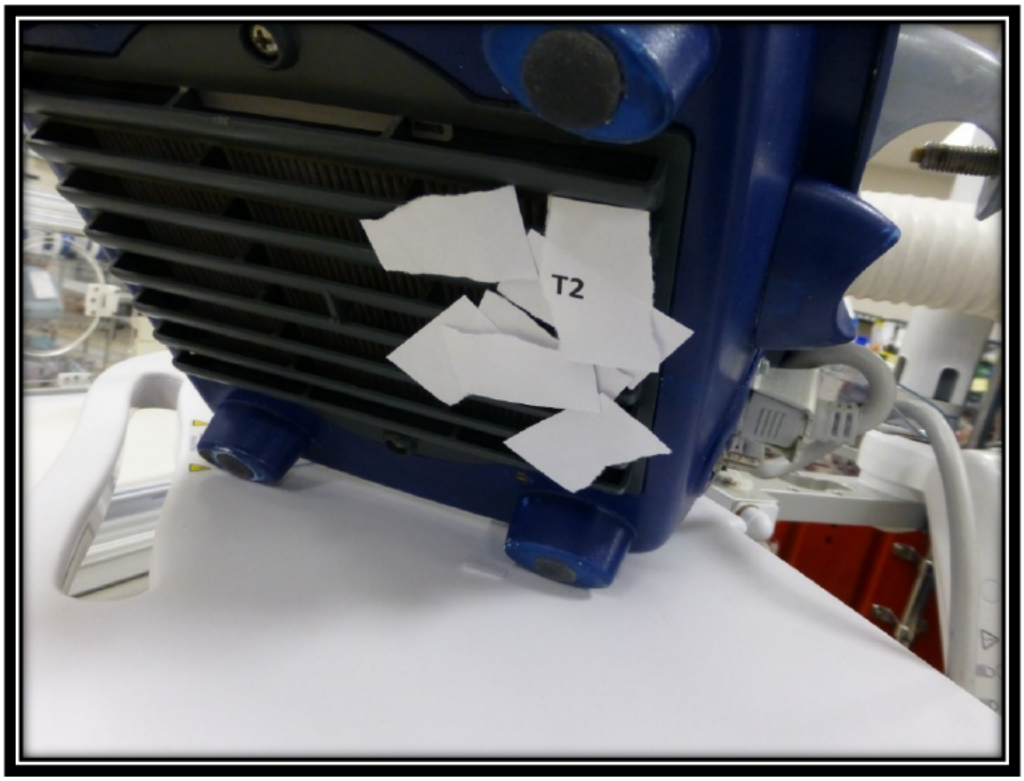


Above: Bottom view after filter cover and filter were removed from the device.

There are two areas of concern with the physical design of the Bair Hugger in terms of the cleanliness of the unit. First is the characteristics of the filter's design. The characteristics of the filter are critical for maintaining a clean flow of air. The second area of concern is the Bair Hugger housing, meaning the enclosure that contains the device. The Bair Hugger housing does not permit cleaning and disinfecting of internal cavities that are continuously positioned in a non-sterile environment on or near the operating room floor. The feet of this exemplar unit had obvious wear on the feet of the unit, showing that it was likely operated on the floor.

[8] Deposition of Corporate Representative Al Van Duren, 308:7.

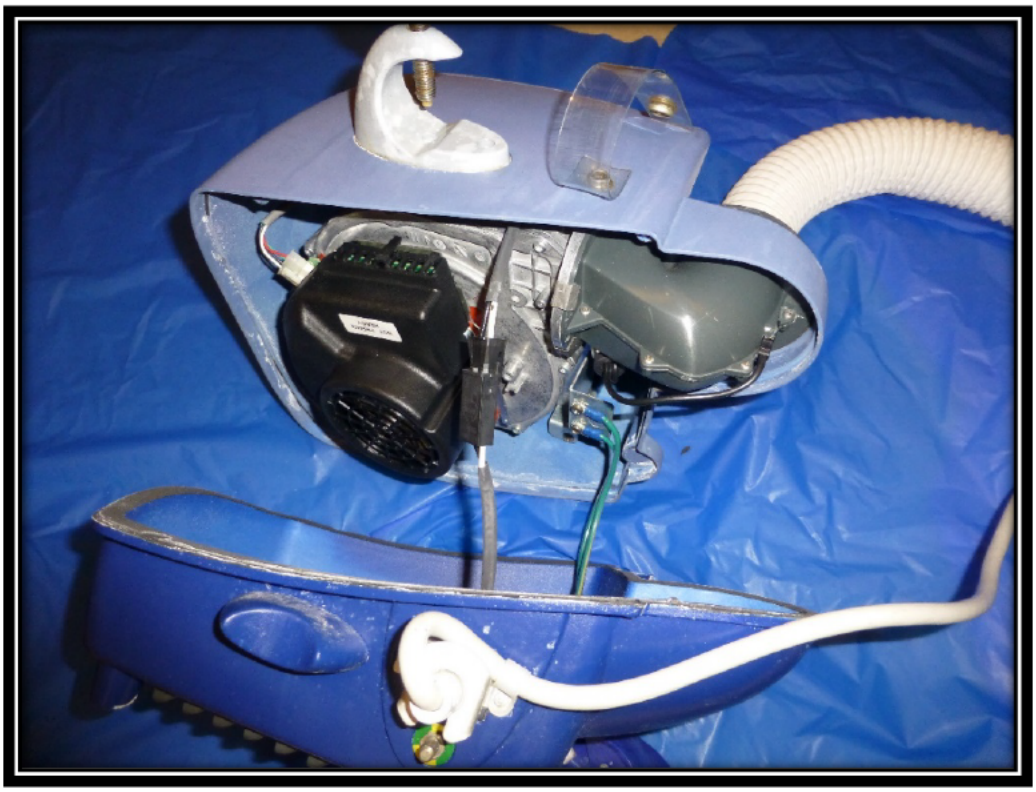
Above: Paper cut outs placed next to the Bair Hugger bottom side. (*held in elevated position for purpose of photography*)



Above: Paper cut outs being sucked by the Bair Hugger fan onto its air intake.

After replacing the filter and filter cover, I continued with a test of the correlation of temperature between points on the blanket and the selected warming mode on the device. [redacted] When I measured several areas of a sample blanket after thirty minutes of operation, I found an average temperature of 36 degrees.

While this used exemplar device was in need of servicing and did not fully reflect the heating performance of a typical Bair Hugger unit, my examination was sufficient to familiarize myself with the operation of the device. I was able to directly observe how the device distributes heat to the patient and how it exhausts warmed air into the surrounding area. Having observed the unit in operation, I then proceeded to disassemble the unit in order to examine its internal design. The device is relatively simple in construction. The enclosure contains the following major components: blower, heating element, electronic controller, temperature sensors, mechanical hose adapter, and user control panel.



[9] 2010 - Bair Hugger temperature testing - 3M00075103.

Once I had completed my examination of the design and operation of the device, I began to review its regulatory history.

5. The Bair Hugger's Troubling Regulatory History

5.1 The 510(k) Clearance Process

In the United States, the Food and Drug Administration (FDA) jurisdiction over products that are intended for use on humans or animals is defined by §201 (h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). [21 USC § 321(h)]. The Act and additional laws that were passed in 1976, the Medical Device Amendments of 1976, and in 1990, the Safe Medical Device Act of 1990 (SMDA), set the core system of the FDA device regulations. The regulation of medical devices differs by a system of risk classifications based on extent of control necessary to insure the safety and efficacy of the device. There are three device classes: Class I, Class II, and Class III. Where class I devices are the least risky. Examples of class I devices include patient scale, bandage, and gloves. Class II devices are those with higher risk than class I and require special controls to assure their safety and effectiveness.

Because Class III devices are mostly life supporting or they present potential unreasonable risk of illness or injury, these class of devices must be not just cleared but actually approved by the FDA before distributing them on the market. They are controlled by premarket approval process (PMA), which means that an application must be submitted with sufficient evidence that is reviewed by the FDA and must have order approved before the device may be legally marketed. Artificial hearts and other implantable devices are example of this class of devices. To obtain approval of their PMA application, the manufacturer must submit detailed information to FDA contained in the premarket approval application that provides reasonable assurance that the device is safe and effective for its intended use with adequate instructions for use. The Bair Hugger device was cleared to market with the designation of a Class II device, thus the Bair Hugger was never subjected to this rigorous approval process of class III device approval.

While Class III devices are required to obtain FDA approval through the more stringent PMA process prior to their distribution on the market, the FDA relies on the premarket notification process required by section 510(k) of the FD&C Act for clearing most class II devices and selected class I devices to market. This process is known as the 510(k) process.

A manufacturer seeking clearance for their new device under 510(k) process must identify a legally marketed "predicate" device that is legally cleared previously by the FDA

and shares substantial equivalency (SE) properties with the new product. Such SE determination[10] means that the both devices have (1) the same intended use and the same technological characteristics as the predicate(s); or (2) the same intended use and different technological characteristics, but the difference does not raise questions related to the new device's safety and effectiveness, and the information so submitted to FDA. This process relies heavily on the manufacturer to provide accurate information.

Ensuring the achievement of device's safety and effectiveness under this regulatory scheme requires the cooperation of every stakeholder involved in the total life cycle management of a medical device's risks. Independent agencies, such as the Institute of Medicine and the Government Accountability Office (GAO) have issued reports over the years that recognized the FDA lacks the capacity to provide adequate review and clearance oversight to the large volume of food, products, and drugs brought to the market. These findings further emphasize the FDA's heavy dependence on medical product manufacturers' compliance with its responsibilities as required in the premarket notification process and section 510(k) of the FD&C Act [21USC §360]. It is the manufacturer's responsibility to ensure its devices are safe, labeled and marketed in accordance with the cleared or approved indications for use.

Moreover, the manufacturer has additional obligations in terms of internal testing. The FDA publication entitled *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff*[11] states under section F. Requests for Performance Data that "Although FDA may rely upon descriptive information alone to address the critical questions in the Flowchart (Decision Points 1 through 4), performance data are typically needed in a Traditional 510(k) to demonstrate the substantial equivalence of a new device to a predicate device. In addition, information on device performance described in labeling or other sections of the 510(k) should be supported with appropriate performance data. The type and quantity of performance data necessary to support a determination of substantial equivalence depend upon the device and/or device type. Performance data may be needed to address a variety of safety and effectiveness issues and may be generated from different types of tests and studies." The FDA relies on the assurances of the manufacturer that appropriate performance testing and validation has occurred.

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[10] *See* The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff, July 28, 2014.

[11] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf#page=25, last visited December 23, 2016))

A device can be marketed in the U.S. after the 510(k) applicant receives a letter (*i.e.*, order) declaring the device substantially equivalent, thereby "clearing" the device for marketing. This is an important distinction in that the device is not technically "approved" by the FDA as with a PMA, but instead is said to be cleared for marketing. The FDA uses the Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles, for evaluating and determining substantial equivalence. These principles act as a guide for the FDA to only request information that is necessary to making substantial equivalence determinations, where "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.[12] The 510(k) process does not reflect an approval by the FDA of the device's safety.

5.2 The Bair Hugger's 510(k) Clearance History

When the first Bair Hugger device was created, the Defendant submitted a 510(k) notification for the product. In 1987, the original Bair Hugger was described as a product "to treat the discomfort of post-operative hypothermia."[13] The Defendant claimed that the Bair Hugger device was "similar in design and function to the Sweetland Bed Warmer and Cast Dryer," a product made by the J.T. Posey Co. from 1937 to 1942.[14]

In identifying the Sweetland Bed Warmer as a substantially equivalent predicate device, the company represented to the FDA that the Bair Hugger had the same intended use. However, the Sweetland Bed Warmer was never used as means to create normothermia during surgical procedures, as later Bair Hugger models were. Moreover, the Bair Hugger and the Sweetland Bed Warmer clearly have different technological characteristics, but my review shows that the company failed to ensure that its new technology did not compromise the device's safety as it began to market its Bair Hugger line of products for use in ultra-clean surgeries.

In the 510(k) submission for the Bair Hugger 505, the Defendant's "Summary of Safety and Effectiveness" acknowledges the risk of airborne contamination.[15] In support of the notion that the Bair Hugger was not an infection risk, the Defendant cited two items from the literature:

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[12] http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf

[13] 1987-09-14 510(k) Notification Letter - 3MBH00047858

[14] *Id.*

[15] 1996-01-10 505 510(k) Summary - 3MBH00047382

Hall, A. *Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room*.

Zink, R.S. *Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room*.

The Hall reference was an abstract presented at a 1991 post-graduate assembly, and not available for review. It was not a published peer-reviewed study, and the details of the abstract or its applicability to this case cannot be determined. The 1993 Zink article was sponsored by the company.[16] That article concerned a small sample test of eight healthy volunteers. Culture plates were placed on a single location on the abdomen. The test was not specific to orthopedic surgical procedures. These references do not provide sufficient clinical validation of the safety of the Bair Hugger 500 series in orthopedic implant surgical procedures, especially in the face of other published research which the Defendant has never provided to the FDA.

In the 510(k) submission for the Model 505, the Defendant identified two features of the device which were intended to mitigate the risk of airborne contamination.[17] First, the Defendant claimed that tape barriers on the blankets would prevent air from entering the surgical site.[18] Second, the Defendant claimed that a high efficiency filter would safeguard against contamination. The Defendant stated that these safety measures were supported by the two studies discussed above, which were conducted on Bair Hugger devices "that have the same air output specifications and the same filter density as the Model 505."[19] However, the modern Bair Hugger 750 does not have the same air output and filter density as the Model 505, and as discussed below, the changes were never properly validated.

5.3 510(k) Clearance of the Bair Hugger Model 750

The Bair Hugger Model 750 was introduced in 2003. The device was cleared to market based in part on the assurance that its filter was substantially equivalent to the

[16] Deposition of Troy Bergstrom, 55:22.
[17] 1996-01-10 505 510(k) Summary - 3MBH00047382
[18] The claim regarding the tape barrier is questionable since the company sells blanket models which do not include a tape barrier. For instance, Bair Hugger underbody blankets do not use tape barriers, yet are marketed for any surgery (Deposition of Troy Bergstrom, at 186:2.). Moreover, it is alleged in a MedWatch report on the Bair Hugger that the tape barriers frequently fail during surgery (MedWatch Report, p. 12 - 3MBH00030637).
[19] 1996-01-10 505 510(k) Summary - 3MBH00047382

Model 505. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[20] Deposition of Gary Hansen, at 30:15.
[21] 2000-05-01 Internal Project Cobra notes - 3MBH01735812
[22] 1999-03-15 Internal email - 3MBH01735994
[23] *Id.*
[24] 2000-05-23 Internal meeting notes - 3MBH00025527

[25] *Id.*
[26] 2000-06-01 Letter to FDA - 3MBH00046971
[27] *Id.*
[28] *Id.*
[29] 2000-06-07 Internal email - 3MBH00497304
[30] *Id.*
[31] 2008-08-08 Internal email -3MBH00022366
[32] 2006-02-26 Filter testing - 3MBH00022367

A letter-to-file is created when a manufacturer makes a non-significant change to an existing legally-marketed product and creates internally documented justifications showing the reasons for change and test results that demonstrate why the change does not impact the safety level or the efficacy of the product.[38] The FDA criteria is that significant change in the design, performance, method of manufacturing or in the intended use of a device requires submission of premarket notification [510(k)]. Furthermore, the FDA defines significant change as modification that could significantly affect the safety or effectiveness of the device or change in its intended use. When the control mechanism of the device is

[33] *Id.*
[34] 2003-08-26 Internal email – 3MBH01031246
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf , last visited February 5, 2017.

changed, or if there is a change in the performance specifications, or if the new material is not being supplied to specification, all raise new issues of safety and efficacy and therefore will require submission of 510(k). When a manufacturer makes a change, it must use one of two forms of compliance with this FDA requirement: (1) letter-to-file when the change is not significant, or (2) submit to the FDA special 510(k) submission or PMA supplement when the change is significant. In either form the manufacturer must demonstrate that the change did not impact safety or efficacy of the device.

[redacted]

[redacted]

[39] Deposition of Corporate Representative Al Van Duren, 87:16; 89:19; 63:14.
[40] *Id*, 306:17.
[41] 2009-01-27 Internal email - 3MBH01807381
[42] 1996-01-10 505 510(k) Summary - 3MBH00047382
[43] Deposition of Karl Zgoda, 43:4.
[44] *Id*, 39:20.

When a manufacturer makes a change in the device's components, the hazard analysis needs to be updated. According to the FDA regulation 21 CFR 820.39(i), this requires that "Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation."[50] The objective of the program -- hazard mitigation and control -- is maintained for the purpose of preventing production of defective devices that can endanger consumers and preventing hazardous devices from reaching the market. The evidence I have reviewed indicates that the Defendant failed to meet these obligations when changing safety components and performance of the device, recklessly endangering patients in the process.

5.4 The 2009 FDA Facility Inspection

In 2009, the Defendant's facility was the subject to a FDA establishment inspection. During this inspection, the FDA engaged the Defendant's Regulatory Compliance Manager, David Westlin, in discussions "about contamination concerns regarding the Bair

[45] 2009-01-20 Test report approving filter change -3MBH00018311
[46] 2012-03-16 Internal email - 3MBH00132832; 2013-10-07 Internal email -3MBH00126140
[47] 2012-03-16 Internal email - 3MBH00132832
[48] 2013-08-24 Internal memorandum - 3MBH01617179
[49] *Id.*
[50] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1).

Hugger temperature warming unit."[51] During this inspection, the FDA was falsely led to believe that that "the warming unit has a 0.2 µm HEPA filter which is in place a secondary safeguard against contamination."[52] As discussed above, the device never had a HEPA filter. Moreover, the sub-HEPA filter that was originally used in the Model 505 was replaced by a drastically less efficient filter in all Bair Hugger models. Yet upon receiving the inspection report, the Defendant did nothing to correct the FDA's misconception, despite providing the FDA a response letter on January 20, 2010 "which replied to the FDA 483 Inspectional Observations."[53]

During the FDA inspection, Mr. Westlin provided the inspector with selected copies of studies which the company felt were favorable on the issue of forced air warming safety. However, Arizant neglected to provide the FDA a fair sample of the body of relevant literature, and it did not provide any studies from the body of literature which had identified an infection hazard from Bair Hugger devices.

The FDA inspection report also made the important observation that "the firm does not have a procedure concerning environmental and contamination controls specific to microbial contamination,"[54] and that "the only cleaning instructions provided with the units" concern exterior cleaning.[55] There are no instructions concerning internal decontamination. I have also reviewed an affidavit signed by five former product engineers of Arizant which states that "in our opinion, there is no practical way to clean and decontaminate the air-flow path of the forced air warming systems."[56] [redacted]

In 2010, one year following the FDA inspection, the company was acquired by 3M. [redacted] Given the documents and testimony I have reviewed, it is my opinion that

[51] 2009-11-30 FDA inspection letter - 3MBH00048067
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] 2010-01-30 Affidavit - 3MBH00005608
[57] Deposition of Corporate Representative Al Van Duren, 291:20.
[58] Deposition of John Rock at 217:17.

the Defendant's 510(k) clearance and subsequent regulatory interactions are not sufficient to ensure the safe use of the Bair Hugger in orthopedic implant surgeries.

6. Review of Literature Finding Risk from the Use of the Bair Hugger

As part of my review of the potential airborne contamination hazard from the Bair Hugger warming system, I reviewed published scientific literature which addressed the issue. I have reviewed a substantial number of scientific studies which examined issues relating to contamination and operating room ventilation. These studies support the conclusion that the Bair Hugger harbors bacterial growth, interferes with operating room airflow, and introduces particles into the sterile field. These studies include:

Infection control hazards of interoperative forced air warming.
Journal of Hospital Infection. Baker, King, and Smith, 2002.

- Heavy growth of bacteria found on forced air warming units.
- Authors found insufficient evidence to justify the routine use of forced air warming during orthopedic surgery.

Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment.
Infection Control and Hospital Epidemiology. Bernards, Harinck, Dijkshoorn, van der Reijden, and van den Broek, 2004

- During an infection outbreak, contaminated dust was found in the interior of a Bair Hugger on the surface of its filter.
- The authors noted that contaminated filters may be serving as a secondary source of transmission.
- After cleaning and filter replacement, the outbreak stopped.

Forced air warming: a source of airborne contamination in the operating room?
Orthopedic Review. Leaper, Albrecht, and Gauthier, 2009.

- Bair Hugger blower surfaces were found to be contaminated with bacterial growth.

- The authors found that the Bair Hugger blows a significant amount of particles into the sterile field.

Don't Forget to Change the Bair Hugger Filter.
American Society of Anesthesiologists Poster Presentation. Gjolaj, Ahlbrand, Yamout, Armstrong, Brock-Utne, 2009.

- Twelve out of twenty-nine Bair Huggers found to have internal bacteria contamination.

- Authors concluded that Bair Hugger may benefit from a microbial filter at the hose end.

Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room.
American Journal of Infection Control. Leaper and Albrecht, 2011.

- Particle testing showed that inadequate filtration allows for internal microbial contamination of the Bair Hugger.

- Contaminates were also detected in the blower air stream.

Forced-air warming and ultra clean ventilation do not mix.
The Journal of Bone and Joint Surgery. McGovern, Albrecht, Belani, Nachtsheim, Partington, Carluke, and Reed, 2011.

- Bubble counts in simulated operations showed that the Bair Hugger mobilizes air from under the table into the surgical site.

- Statistical analysis of nearly 1,500 orthopedic patients showed elevated infection odds ratio of 3.8 during a period when the Bair Hugger was used.

Do forced air patient warming devices disrupt unidirectional downward airflow?
The Journal of Bone and Joint Surgery, Legg, Cannon, and Hamer, 2012.

- Significantly increased temperature and particle count over the surgical site during Bair Hugger operation.

Effect of forced air warming on the performance of operating theatre laminar flow ventilation.
Anesthesia. Dasari, Albrecht, and Harper, 2012.

- Significantly increased temperatures during the use of forced air warming.

- Forced air warming generates convection activity near the surgical site.

Forced-air patient warming blankets disrupt unidirectional airflow.
The Journal of Bone and Joint Surgery. Legg and Hamer, 2013.

- The authors used helium bubbles to visualize airflow over a simulated knee replacement.

- The authors concluded that forced air warming can significantly disrupt unidirectional air-flow and draw particles from the potentially contaminated area below the sterile field.

Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance.
Anesthesia & Analgesia. Belani, Albrecht, McGovern, Reed, and Nachtsheim, 2013.

- Heat currents mobilized bubbles into the surgical site.

- Significant increase in bubble counts were found during Bair Hugger use.

Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne contamination emissions.
American Association of Nurse Anesthetists Journal. Reed, Kimsberger, McGovern, and Albrecht, 2013.

- Authors tested filters and discovered lowered filtration efficiency.

- 100% of Bair Huggers tested contained bacterial growth.

- Bair Hugger units were emitting significant particle counts from the hose end.

- Authors recommended HEPA filtration or re-designing the unit to allow for internal cleaning.

Infection control hazards associated with the use of forced air warming in operating theatres.
Journal of Hospital Infection. Wood, Moss, Keenan, Reed, and Leaper, 2014.

- After review of existing literature, the authors recommended that facilities consider the use of alternative warming technologies.

Forced air warming device failure resulting in smoke and soot on a surgical patient.
M.D. Anderson Poster Presentation. Tsai, Van Meter, Dang, Potylchansky, Moon, 2016.

- Case study of a Bair Hugger 750 unit which sucked liquid into the interior, causing an electrical short.

- Smoke was noticed in the surgical field, and black punctate spots were found on sheets and patient skin.

- Spots were in the pattern of perforation holes on Bair Hugger blanket, showing that particles traveled through the system and out of the blanket.

These studies provide substantial evidence of the patient safety risk posed by the Bair Hugger. While the individual results of these studies are not definitive, collectively they support the conclusion that that Bair Hugger has the potential to cause surgical site infections in orthopedic surgeries.

7. Defendant's Refusal to Mitigate Patient Risk

7.1 Awareness of the patient safety risk

In coming to my opinions in this case, I had the unique benefit of reviewing internal confidential documents generated by the Defendant concerning the issue of airborne contamination from the use of the Bair Hugger. When I am conducting a hazard analysis of a medical device outside of the litigation setting, I do not typically have access to these

kinds of materials when forming opinions about the risk of a product. The internal documents of a company help provide a more complete picture of the device itself, the research conducted on the device, and information which would otherwise be withheld from the public.

[redacted]

[redacted]

7.2 Rejected attempts to solve the contamination problem

[redacted]

[59] 2011-09-08 Presentation - 3MBH00109033
[60] Deposition of Corporate Representative Al Van Duren, 31:20.
[61] 2013-08-03 Internal email - 3MBH00580475
[62] 2012-03-16 Internal email - 3MBH00132832; 2013-10-07 Internal email -3MBH00126140; 2015-05-04 Internal email - 3MBH02117830.
[63] 2012-03-16 Internal email - 3MBH00132832
[64] 2008-07-31 Internal meeting notes - 3MBH00022877

[redacted]

[redacted]

[redacted]

[redacted]

[65] 2009-05-20 Powerpoint presentation - 3MBH00022625
[66] *Id.*
[67] *Id.*
[68] 2009-06-15 Test report - 3MBH00025006
[69] *Id.*

[redacted]

[redacted] (Lansdown, *Silver in Health Care: Antimicrobial Effects and Safety in Use* (2006)[71]; Thurman, *The Molecular Mechanisms of Cooper and Silver Ion Disinfection of Bacteria and Viruses* (1989)[72]; Feng, *A mechanistic study of the antibacterial effect of silver ions on Escherichia coli and Staphylococcus aureus* (1999)).[73] [redacted]

[redacted]

[70] *Id.*
[71] 2006 - Lansdown - 3MBH00536470
[72] 1989 - Thurman - 3MBH00846631
[73] 1999 - Feng - 3MBH00026841
[74] 2009-05-20 Powerpoint presentation - 3MBH0002262
[75] 2009-10-02 Internal email - 3MBH00024682
[76] 2014-03-05 Blower Hose Ideation Powerpoint - 3MBH00630074

[redacted]

8. Other Potential Alternative Designs

In reviewing this patient warming device, I have considered alternative designs to the Bair Hugger. There are many different ways to design a patient warming device, and it is my opinion that, more likely than not, there are safer alternative designs which are as effective as the Bair Hugger. In the field of biomedical engineering, the implementation of a safer alternative design for a medical product could take three different forms:

- *Addition*: In some cases, a safer alternative design solution can be achieved by the addition of a component, with little or no modification of the underlying design concepts.

- *Removal*: In some other cases, a safer alternative design solution can be achieved by the removal of a problematic component when it is not essential for the operation or clinical needs of the device.

- *Re-Engineering*: In still other cases, a safer alternative design solution will require that components of the device be fundamentally re-engineered. In doing so, the re-engineering process can incorporate alternative technology if that technology can achieve the same device design goals in a safer way. The re-engineered device should be able to function in the same clinical environment and fulfill the same clinical purpose. If the re-engineered device performs a different clinical function or if it is inappropriate in the same clinical role, then the engineer has created a substantially different kind of product and not an alternative design.

One alternative design is to modify the method by which the device transfers heat to the patient. While the Bair Hugger uses airflow through a blanket to provide both conductive and convective heat, a similar result can be achieved using a electric heating mattress design to provide primarily conductive heat without convection. A resistive heating mattress can transfer heat without affecting operating room airflow. One such commercially viable example is the VitaHEAT UB3. In October of 2016, 3M announced

that it reached an agreement with VitaHEAT to be the exclusive distributor of its product in the United States.[77] The VitaHEAT UB3 product transfers heat through a conductive warming mattress designed to be placed under the patient, allowing the clinician to adjust the temperature.[78] The makers of VitaHEAT note that "[t]here is no forced air to warm up clinicians tending the patients."[79] VitaHEAT states that its "conductive heat warms the patients without circulating air."[80] Dr. Daniel Sessler, a clinical consultant of 3M, concluded that resistive heating mattress designs are equally effective to the Bair Hugger's forced-air blanket in maintaining temperature in patients undergoing surgery and has published studies on his findings. Those studies concluded that "core temperatures were no different, and significantly noninferior, with underbody resistive heating than upper-body forced-air warming."[81]

Another alternative design concept which is more likely than not safer and as effective as the Bair Hugger is the design employed by the Berchtold Tablegard system. Like the Bair Hugger, the Tablegard system uses forced air through a blower, providing heated air to combat perioperative hypothermia. However, the Tablegard system uses a closed recirculation system to provide conductive warming with no introduction of airflow to the sterile field or contact with the patient's skin.[82] Like the Bair Hugger, the Tablegard system "is intended for use on operating tables, surgical and diagnostic surfaces in hospitals or surgical centers to prevent and treat hypothermia."[83] This air-circulating mattress design is also cleared "to reduce the occurrence of pressure ulcers."[84]

[77] VitaHEAT marketing materials.
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] Deposition of Daniel Sessler, 125:2.
[82] Tablegard marketing materials.
[83] Tablegard 510(k) Summary - K080763.
[84] *Id.*

The Tablegard system was cleared by the FDA in 2008 as substantially equivalent to the Bair Hugger Model 750. As stated in filings made with the FDA:

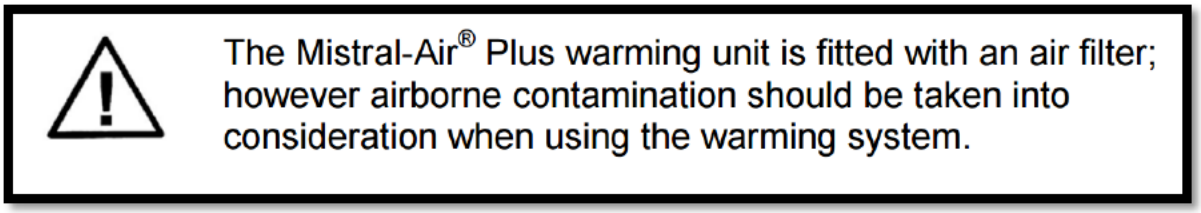
> The differences between the TableGard Pressure Relieving Patient Warming Mattress and the predicate devices [including the Bair Hugger] are minimal. The predicate devices are all external, thermal regulation systems that consist of a device that is placed in contact with the patient, and connected to a control unit that provides physician determined temperature controls.[85]

It is my opinion that the design concept used by the Tablegard system is more likely than not safer and as effective as the Bair Hugger. Another related alternative design would be the development of a closed recirculation system similar to that envisioned in the Defendant's 2014 design proposals, discussed above. It is my opinion that more likely than not, 3M could have developed a prototype along these lines which would have been safer and as effective as the Bair Hugger.

Another option which would mitigate some of the hazard posed by the Bair Hugger would be the use of a forced-air warming device with a HEPA filter. Some devices, such as the Mistral-Air Warming System, feature a HEPA filter which provides 99.97% efficiency at .3 microns.[86] While the use of a forced-air warming device still poses a risk due to disruption of the sterile surgical field and introduction of airborne particles to the wound, a HEPA filter would help mitigate some of the risk by preventing the warming unit from collecting and incubating bacteria of its own. The Defendant also could have helped mitigate this risk in the Bair Hugger by adopting the "Project Ducky" prototype, which included a HEPA filter and antimicrobial hose coatings. Therefore, while far from optimal, devices with HEPA filters and/or antimicrobial technologies would have been a safer alternative.

[85] *Id.*
[86] Mistral Brochure.

Additionally, the Mistral-Air system features one substantial improvement in terms of product labeling. The Service Manual of the Mistral-Air system contains a specific warning about the potential for airborne contamination:



[87]

This warning is especially relevant to orthopedic procedures, which are conducted under rigorous clean conditions. The warning appears in the Safety Precautions section of the manual. Also, the warning is accompanied by a symbol, in this instance an exclamation mark, which is a familiar measure to draw the user's attention to the urgency of the warning. These kinds of warnings are reviewed by biomedical engineers when selecting and placing hospital equipment. If the Bair Hugger had included this kind of warning, for example, its clinical customers could have scrutinized the Bair Hugger's effect on operating room airflow and been in a better position to make the decision to curtail the use of the device in high-risk orthopedic implant procedures.

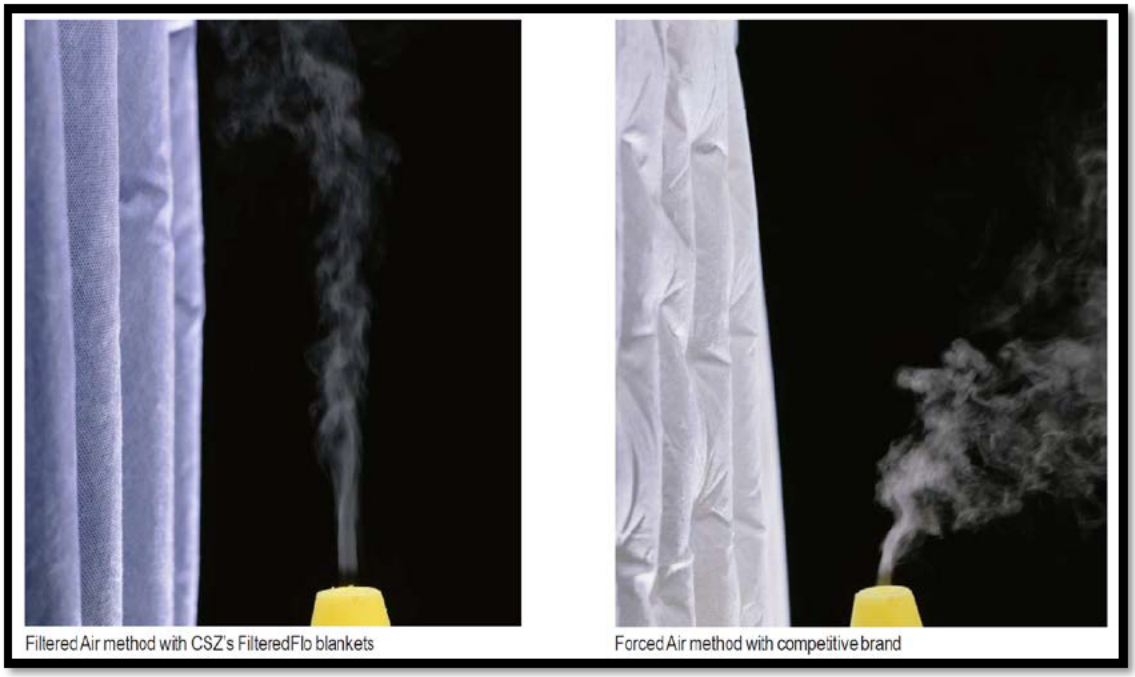
FDA bluebook guidance documents instruct manufacturers to use a warning in product labeling for "potential safety hazards" under the following circumstances:

- Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved.[88]

[redacted] It is my opinion that the removal of an airborne contamination warning from the Bair Hugger makes the device unreasonably dangerous.

[87] Mistral MA-1100 Service Manual.
[88] https://www.fda.gov/RegulatoryInformation/Guidances/ucm081368.htm
[89] Deposition of Corporate Representative Al Van Duren, 313:22; 316:4.
[90] *Id,* 316:8.
[91] *Id,* 316:14.

There are other air-based warming products which are designed with the intention of reducing the disruption of theater ventilation or the potential for contamination. For example, the WarmAir device, manufactured by Cincinnati Sub Zero, is marketed with a "FilteredFlo blanket" which features a "non-woven delivery surface." These blankets require "no perforation," which is designed to avoid "unwanted and potentially dangerous particles in your operating room."[92] The manufacturer states that the blanket design also "permits use of a lower velocity blower to supply gently moving, clean air" which "minimizes air currents that may spread contaminants to your patient." Published literature shows that the WarmAir device produces significantly less airflow than the Bair Hugger but was equally effective in maintaining perioperative normothermia in patients undergoing major abdominal and orthopedic surgery.[93] Is it my opinion that the design concepts and goals pursued could be feasibly integrated into a patient warming device that would help address and mitigate the risk of airborne contamination.



Above: WarmAir marketing materials

[92] WarmAir marketing materials.
[93] https://www.ncbi.nlm.nih.gov/m/pubmed/18566199/ , last visited February 18, 2017.

However, the most prudent option is to avoid all air-circulating devices. The U.S. Centers for Disease Control has recently stated that equipment capable of circulating air should not be used in operating rooms. In 2015, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) stated that "[n]othing that blows air should be in an operating theater, if possible."[94] As result of my investigation, it is my opinion that the most appropriate alternative designs for operative patient warming devices are those which do not circulate air in the surgical environment.

9. Summary of Opinions

It is my opinion that the Defendant violated Section 301 of the Food & Drug Act, which prohibits selling a medical device in the United States that is not safe and adequately labeled. *See* 21 U.S.C. § 331. It is also my opinion that the device is misbranded because its labeling fails to contain adequate instructions for use including appropriate warnings. Additionally, Section 301 of the Act prohibits the following acts relating to the misbranding of a medical device, all of which I conclude were violated by the Defendant:

> (a) The introduction or delivery for introduction into interstate commerce of any device that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any device in interstate commerce.
>
> (c) The receipt in interstate commerce of any device that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
>
> …
>
> (g) The manufacture, within any Territory of any device that is adulterated or misbranded.
>
> …
>
> (q) …(2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

[94] HICPAC Meeting Minutes, November 5-6, 2015, p. 27

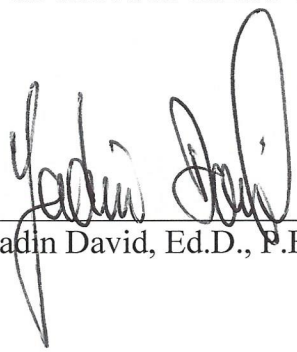
In addition, it is my opinion that the Defendant failed to meet its obligation for good manufacturing practices under FDA regulations. All medical device manufacturers have a responsibility to meet Good Manufacturing Practices and to market safe products. As emphasized above, a clearance under 510(k) is not an approval by the federal government that the product is safe in general or safe for any particular use. In addition, it appears that the information about the device which has been given to the FDA over the years has not been accurate or complete. Furthermore, the Defendant failed in its obligation under the regulations to perform adequate safety validation prior to marketing the device. Finally, a significant body of scientific literature has identified an infection hazard from the use of the Bair Hugger, and the Defendant chose to dismiss this evidence. In fact, the Defendant went out of its way to discourage research or scrutiny on this topic.

The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer; the manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information. To fulfil this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the healthcare community and to consumers. It is my opinion that the Defendant consciously failed to meet these responsibilities.

It is also my opinion that Defendant failed to follow common practices in the medical device manufacturing industry by failing to adequately investigate the issue of the Bair Hugger's impact on orthopedic implant surgeries and adequately mitigate this hazard. It was the responsibility of the Defendant's senior leadership and the device's life-cycle quality management system program to ensure that evaluation of all potential hazards and their impact were documented and addressed and that each of the risks was subjected to evaluation and actions to mitigate patient risk. By failing to do so, the Defendant showed a reckless disregard for patient safety.

In sum, I conclude that the Defendant did not act as a reasonably prudent medical device manufacturer would act in response to these issues, and that the Defendant willfully failed to meet its obligations to adequately ensure patient safety. I also conclude that the Defendant did not provide adequate warnings and precautions about the potential for airborne contamination, despite its awareness of the likelihood of joint infection. Finally, when viewed from a biomedical engineering risk analysis perspective, it is my opinion

that the Bair Hugger presents an unreasonable danger in orthopedic operating rooms because the device more likely than not presents an infection hazard during orthopedic implant surgeries.



Yadin David, Ed.D., P.E., C.C.E.

MATERIALS REVIEWED

Depositions:

Gary Hansen, Director of Research & Development
Karl Zgoda, Lead Product Engineer, Bair Hugger 750
Dave Westlin, Regulatory Affairs Manager
Teri Woodwick Sides, VP of Product Development
John Rock, Director of Legal Affairs
Troy Bergstrom, Public Relations
Al Van Duren, Corporate Representative
Suzanne Danielson, Corporate Representative
Daniel Sessler, Researcher and Consultant

Documents Produced by 3M:

3MBH00000826
3MBH00002262
3MBH00002413
3MBH00002647
3MBH00002792
3MBH00005602
3MBH00005608
3MBH00007797
3MBH00008941
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3MBH00047858
3MBH00048067
3MBH00048069
3MBH00052987
3MBH00053467
3MBH00053468
3MBH00075103
3MBH00109033
3MBH00119208
3MBH00126140
3MBH00132832
3MBH00135389
3MBH00497304
3MBH00536470
3MBH00544754
3MBH00580475
3MBH00630074
3MBH00846631
3MBH01031246
3MBH01223897
3MBH01254006
3MBH01286161
3MBH01330587
3MBH01485746
3MBH01617179
3MBH01735812
3MBH01735994
3MBH01807381
3MBH01937959
3MBH01983525
3MBH02117830

Other Documents:

Bair Hugger Therapy Product Specifications

Bair Hugger 750 Service Manual

HICPAC Meeting Minutes, November 5-6, 2015

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff, July 28, 2014

FDA Establishment Inspection Report (EIR), Nov. 17, 2010

FDA QS and GMP Reference Materials

VitaHEAT marketing materials

VitaHEAT 510k Summary - K132454

Tablegard marketing materials

Tablegard 510(k) Summary - K080763

Mistral marketing materials

Mistral MA-1100 Service Manual

Mistral Air 510k Summary - K101705

WarmAir marketing materials

WarmAir 510k - K123946

International Consensus Meeting on Periprosthetic Joint Infection

Doctor Says a Device He Invested Poses Risk, New York Times, Dec. 24, 2010

ASHRAE Standard 62.1-2016

MERV Rating Chart

Expert Reports:

Dr. Said Elghobashi, Ph.D, D.Sc.
Dr. William Jarvis, M.D.
Dr. Michael Stonnington, M.D.

Websites:

https://www.mitre.org/publications/systems-engineering-guide/acquisition-systems-engineering/risk-management/risk-management-approach-and-plan

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf

http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf

https://www.fda.gov/RegulatoryInformation/Guidances/ucm081368.htm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1

https://www.ncbi.nlm.nih.gov/m/pubmed/18566199/ - "Comparison of two convective warming systems during major abdominal and orthopedic surgery"

https://www.youtube.com/watch?v=BKFl2rINa9g – "Airborne Contamination in the Operating Room"

https://www.youtube.com/watch?v=hdtiBgUFzdc – "Forced-air warming destroys Laminar air-flow"

https://www.youtube.com/watch?v=9XxtZNmMXWo – "TableGard Patient Care System"

https://www.youtube.com/watch?v=asH_zRY7Q78 – "Mistral Air Blankets Plus"

Published Literature:

Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room.
Anesthesia & Analgesia. Zink and Iaizzo, 1993.

Infection control hazards of interoperative forced air warming.
Journal of Hospital Infection. Baker, King, and Smith, 2002.

Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment.
Infection Control and Hospital Epidemiology. Bernards, Harinck, Dijkshoorn, van der Reijden, and van den Broek, 2004

Forced air warming: a source of airborne contamination in the operating room?
Orthopedic Review. Leaper, Albrecht, and Gauthier, 2009.

Don't Forget to Change the Bair Hugger Filter.
American Society of Anesthesiologists Poster Presentation. Gjolaj, Ahlbrand, Yamout, Armstrong, Brock-Utne, 2009.

Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room.
American Journal of Infection Control. Leaper and Albrecht, 2011.

Forced-air warming and ultra clean ventilation do not mix.
The Journal of Bone and Joint Surgery. McGovern, Albrecht, Belani, Nachtsheim, Partington, Carluke, and Reed, 2011.

Do forced air patient warming devices disrupt unidirectional downward airflow?
The Journal of Bone and Joint Surgery, Legg, Cannon, and Hamer, 2012.

Effect of forced air warming on the performance of operating theatre laminar flow ventilation.
Anesthesia. Dasari, Albrecht, and Harper, 2012.

Forced-air patient warming blankets disrupt unidirectional airflow.
The Journal of Bone and Joint Surgery. Legg and Hamer, 2013.

Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance.
Anesthesia & Analgesia. Belani, Albrecht, McGovern, Reed, and Nachtsheim, 2013.

Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne contamination emissions.
American Association of Nurse Anesthetists Journal. Reed, Kimsberger, McGovern, and Albrecht, 2013.

Infection control hazards associated with the use of forced air warming in operating theatres.
Journal of Hospital Infection. Wood, Moss, Keenan, Reed, and Leaper, 2014.

Forced air warming device failure resulting in smoke and soot on a surgical patient.
M.D. Anderson Poster Presentation. Tsai, Van Meter, Dang, Potylchansky, Moon, 2016.